**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**
**CHARLESTON DIVISION**

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| **IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LIGITATION** | **Master File No. 2:12-MD-02327**<br>**MDL No. 2327**<br><br>**JOSEPH R. GOODWIN**<br>**U.S. DISTRICT JUDGE** |
| **THIS DOCUMENT RELATES TO:**<br><br>**ETHICON WAVE 1 PLAINTIFFS LISTED ON EXHIBIT A** | |

**PLAINTIFFS' MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF DR. CYNTHIA BERGMAN**

In support of their motion to exclude expert Cynthia Bergmann ("Dr. Bergmann"), Plaintiffs state as follows:

## INTRODUCTION

Dr. Bergmann is an Obstetrician/Gynecologist, and Plaintiffs do not challenge her qualifications as such.[1] However, Dr. Bergmann offers opinions in this case that exceed the bounds of her qualifications and are founded on insufficient facts and unreliable methodology.[2] No jury should hear any expert testimony that is not reliable. Dr. Bergmann's experience in the field of Gynecology does not render all of her opinions admissible. The admissibility of Dr. Bergmann's unfounded opinions is both contrary to law and presents a serious risk of confusing the issues and misleading the jury in this case.[3] As this Court noted,"[j]ust because an expert may be 'qualified .

[1] Curriculum Vitae of Dr. Bergmann (attached as Ex. B).
[2] *See Phelan v. Synthes*, 35 Fed. Appx. 102, 105(4th Cir. 2002) (the reasoning or methodology underlying testimony must be scientifically valid and able to be properly applied to the facts in issue.)
[3] *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)("[T]he court must recognize that due to the difficulty of evaluating their testimony, expert witnesses have the potential to 'be both powerful and quite misleading.')(citing Daubert, 509 U.S. at 596).

. . by knowledge, skill, experience, training or education' does not necessarily mean that the opinion that the expert offers is 'the product of reliable principles and methods' or that the expert 'has reliably applied the principles and methods to the facts of this case.'"[4] Accordingly, Dr. Bergmann should be prevented from offering testimony or opinions that exceed those permitted under *Daubert* and its progeny.

## LEGAL STANDARD

Under Rule 702 of the Federal Rules of Evidence, as interpreted by the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), an expert witness may be qualified by "knowledge, skill, experience, training or education." Fed. R. Evid. 702. The witness's testimony also must represent "scientific knowledge," meaning that it is supported by appropriate validation; and it must assist the jury, meaning that it must be relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). Expert testimony is admissible if the expert is proven to be qualified and said testimony (1) "will help the trier of fact to understand the evidence or to determine a fact in issue," (2) is "based upon sufficient facts or data," (3) is "the product of reliable principles and methods" and (4) has been reliably applied "to the facts of the case." Fed.R.Evid. 702. Opinion evidence may be admitted if it "rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597. In the end, an expert's testimony is admissible if it "rests on a reliable foundation and is relevant." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999).

The duty rests with Dr. Bergmann to proffer expert testimony and "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Maryland Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). Even if Dr. Bergmann is qualified and the testimony is reliable, "testimony which does not relate to any issue

[4] *Cisson v. C.R. Bard, Inc.*, MDL No. 2187, 2013 U.S. Dist. LEXIS 78061, *42-43 (S.D.W.V. 2013).

in the case is not relevant and, ergo, non-helpful." *In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig.*, 2:12-MD-02327, 2014 WL 186872 (S.D.W. Va. Jan. 15,2014) *reconsideration denied*, 2014 WL 457544 (S.D.W. Va. Feb. 3, 2014). In other words, Dr. Bergmann can only offer testimony that is "fit" for the case, and there must be a "valid scientific connection to the pertinent inquiry as a precondition to admissibility. *Id.*

## ARGUMENT

Dr. Bergmann opines on many areas which exceed her expertise or experience as a gynecologist and offers many opinions which are not reliable. Dr. Bergmann not only disagrees with Ethicon's own internal documents, but she also disagrees with herself on several occasions. As such, Dr. Bergmann's self-contradictory opinions are unreliable on this matter and should be limited or excluded entirely.

### I. DR. BERGMANN'S OPINIONS REGARDING ANY INTERNAL ETHICON DOCUMENTS SHOULD BE EXCLUDED BECAUSE DR. BERGMANN NEVER REVIEWED THESE DOCUMENTS PRIOR TO SIGNING HER REPORT OR ATTENDING HER DEPOSITION

Despite including numerous pages of internal Ethicon documents on her list of "reliance materials,"[5] Dr. Bergmann testified that she has never seen or looked at any internal Ethicon documents or documents with Ethicon bates numbers.

> Q Did you review Ethicon e-mails as part of your preparing and writing your report?
>
> A No.[6]
>
> . . .
>
> Q Did you look at any internal Ethicon documents?
>
> A No.[7]
>
> . . .

[5] Cynthia Bergmann Reliance List, attached hereto as Exhibit D at 26-34.
[6] Deposition of Dr. Cynthia Bergmann, dated March 15, 2016, attached hereto as Exhibit E, at 87:14-16.
[7] *Id.* at 94:12-13.

> Q But you haven't seen any documents that are internal Ethicon e-mails like this, which have a Bates number at the bottom, up until today, correct?
>
> A Correct.[8]

Dr. Bergmann should therefore be prohibited from testifying about any Ethicon documents or their contents because she has not reviewed or seen them prior to the service of her report or attending her deposition.

## II. DR. BERGMANN IS UNQUALIFIED TO OFFER OPINIONS REGARDING PUBOVAGINAL SLINGS, THE MESH MATERIAL USED IN THE TVT DEVICE, FEASIBLE ALTERNATIVES AND THE ASSOCIATED RISKS AND COMPLICATIONS

### A. Dr. Bergmann is unqualified to opine on the morbidity of the pubovaginal sling procedure or associated complications because she has never been trained to perform the pubovaginal sling procedure and does not perform pubovaginal sling procedures in her practice.

Dr. Bergmann opines that pubovaginal slings "share the same complications as the TVT procedure, with the exception of mesh exposure/erosion" and that the "TVT procedure is a much less morbid procedure than the . . . pubovaginal sling procedure."[9] However, Dr. Bergmann testified that she was not trained in how to perform the pubovaginal sling procedure, only her partner was,[10] and that she does not use pubovaginal slings in her practice.[11] Having no training or experience in pubovaginal slings, Dr. Bergmann is therefore unqualified to offer any opinions about the pubovaginal procedure, its alleged morbidity as compared to the TVT procedure, or the risks associated therewith under *Daubert* or the Federal Rules of Evidence.[12]

### B. Dr. Bergmann is unqualified to offer opinions regarding the type of mesh used in the TVT device, feasible alternatives, and the associated risks and

[8] *Id.* at 102:11-14; *See* also 100:6-25.
[9] Report Regarding the Ethicon TVT Incontinence Sling, attached hereto as Exhibit C, at 15.
[10] *Id.* at 3; Ex. E at 25:23-25
[11] *Id.* at 46:10-16.
[12] *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), an expert witness may be qualified by "knowledge, skill, experience, training or education." Fed. R. Evid. 702.

**complications because she does not know what mesh the TVT device is made of and contradicts her own opinions on this topic**

Dr. Bergmann opines that "Plaintiffs' experts also contend that **alternative mesh materials such as** Ultrapro, Vypro, **Gynemesh PS**, or other larger-pore, lighter-weight meshes would have reduced the plaintiff's risk of complications. However, there is no peer-reviewed published data showing the feasibility of the use of those meshes in the context of an SUI sling . . . **The Prolene mesh used in the TVT product** is the most studied mesh used in incontinence surgery and has the most safety and efficacy data supporting it."[13] [emphasis added]. However, at her deposition, Dr. Bergmann testified that the TVT sling *is made of Gynemesh*, not Prolene.

> Q Is the TVT made of Gynemesh?
>
> A Yeah, it's the same material[14]

Defense counsel attempted to rehabilitate Dr. Bergmann on this point, but Dr. Bergmann only reiterated her belief that the TVT device is made of Gynemesh.

> Q Dr. Bergmann, there was a question earlier about Gynemesh. Is it your understanding that the TVT mesh is different than Gynemesh PS?
> A Yeah, because there's several different grades of Gynemesh is my understanding, so I know it's. . ."[15]

Dr. Bergmann cannot possibly be qualified to testify about the qualities of the mesh material used to make the TVT sling when she does not know that the TVT device is made of Prolene mesh. Further, Dr. Bergmann's testimony contradicts her own report which states that Gynemesh is an *alternative* material to Prolene (the material of which the TVT device is actually made). Dr. Bergmann's opinions on this point are therefore unreliable and should be excluded.

**C. Dr. Bergmann is not qualified to render opinions on Ethicon's training programs because she only attended two courses in 2001, has never taught**

[13] Ex. C at 16.
[14] Ex. E at 14:8-9; in fact in her CV Dr. Bergmann states she is a trainer for "Gynecare Gynemesh" when in fact she is referring to being a proctor for the TVT device. Ex. B at 4, Ex. E at 14:1-7.
[15] *Id.* at 117:22-118:1.

**other physicians as an Ethicon proctor and has not reviewed any internal Ethicon documents**

Dr. Bergmann opines on Ethicon's training programs on page 20 of her report.[16] However, she is not qualified to offer opinions on Ethicon's training or physician education. Dr. Bergmann has only attended two Ethicon training classes, both as a student in 2001 or 2003.[17] Dr. Bergmann does not have any of the training materials she received in those training sessions.[18] Dr. Bergmann has never taught other physicians as a trainer for Ethicon regarding the TVT device.[19] Additionally, as stated above, Dr. Bergmann has not reviewed any internal Ethicon documents or materials. Dr. Bergmann therefore has no way of knowing what is included in Ethicon's training or physician education for the TVT device outside of the two classes she attended (that either occurred in 2001 or 2003 – Dr. Bergmann's testimony here is conflicting). Dr. Bergmann cannot possibly be qualified to testify about the adequacy or contents of Ethicon's training or physician education when she does not know what that training entails and has not viewed any documents associated with said training or physician education. Her opinions on these topics are unreliable, Dr. Bergmann is not qualified to offer them, and these opinions should therefore be excluded.

## III. DR. BERGMAN'S OPINIONS REGARDING PARTICLE LOSS SHOULD BE EXCLUDED BECAUSE DR. BERGMANN DOES NOT KNOW WHAT THE TERM PARTICLE LOSS MEANS AND HER TESTIMONY CONFLICTS WITH DEFENDANT'S OWN DOCUMENTS

In her report, Dr. Bergmann opines that "[i] n more than 250 uses of the TVT devices in my career, I have not seen any clinically significant particle loss in my patients. Even if it were

[16] Ex. C.
[17] Ex. E at 18:5-12; Deposition of Dr. Cynthia Bergmann dated March 15, 2016 (Daino v. Ethicon) attached hereto as Exhibit F, at 48:18-24. Dr. Bergmann states in her report that she was trained in 2001, but in her deposition states she was trained on the TVT in 2003.
[18] Ex. E at 36:1-3.
[19] Ex. E at 40:24-41:5; Ex. C at 2.

the case that the mesh lost particles in the patient, the particles lost would be the Prolene polypropylene suture material that has been safely and effectively used in millions of patients over the course of many decades."[20] Dr. Bergmann further testified that she had not seen any particle loss with her naked eye with the TVT device,[21] but admits there may be particle loss which she cannot see.[22]

However, Dr. Bergmann's opinion conflicts with Ethicon's own documents which state that particle loss did in fact occur and in fact particle loss with the TVT device was the reason that Defendant switched to laser cut mesh in its TVT device.[23] Dr. Bergmann further testified that she could not offer any opinions on Defendants document related to particle loss because she didn't know what Defendant's definition of particle loss was.[24] Dr. Bergmann also admitted that she does not know if her definition of particle loss is the same definition used by Plaintiffs' experts[25] and that she has not seen any of the internal Ethicon documents referenced by Plaintiffs' experts relied on for their opinions regarding particle loss. Dr. Bergmann's opinions regarding particle loss and any rebuttal of Plaintiffs' experts' opinions on particle loss are therefore unreliable and should be excluded.

## IV. DR. BERGMANN'S OPINIONS REGARDING DEGRADATION ARE MERE IPSE DIXIT AND SHOULD BE EXCLUDED

Dr. Bergmann opines that she "ha[s] not seen clinically significant degradation of the TVT mesh in my practice, nor have I seen clinically significant degradation described in the published literature, even in those patients on whom I re-operated following a prior midurethral

[20] Ex. C at 16.
[21] Ex. E at 94:14-22; 97:1-12
[22] *Id.* at 96:1-5.
[23] *Id.* at 97:25-100:18; 102:15-103:19.
[24] *Id.* at 100:14-25.
[25] *Id.* at 101:1-12.

sling procedure. If the TVT device degraded as plaintiffs' witnesses claim, one would not see the excellent long-term efficacy and safety shown in the published medical literature."[26] However, Dr. Bergmann's only support for this opinion is "common sense."

> Q In the next sentence of your report you state: "If the TVT device degraded, as plaintiff witnesses claim, one would not see the excellent long-term efficacy and safety shown in the published medical literature." Can you tell me how you reached that conclusion?
>
> A Just common sense. If it were really falling apart why would it last so long? And the analogy is we used to use absorbable sutures to do Kelly plication procedures for stress incontinence. Those fail, the sutures get re-absorbed.[27]

"Common sense" is not meaningful scientific support under *Daubert* or the Federal Rules of Evidence, and Dr. Bergmann's opinions regarding degradation should not be heard by any jury. *Daubert*, 509 U.S. at 590 (in the context of Rule 702, knowledge "connotes more than subjective belief or unsupported speculation."). Dr. Bergmann has not shown that her opinions regarding degradation are reliable or scientifically sound. They are mere *ipse dixit* and should therefore be excluded.

## V. DR. BERGMANN IS UNQUALIFIED TO OFFER OPINION AS TO THE ADEQUACY OF THE TVT INSTRUCTIONS FOR USE AND WARNING OF DYSPARUENIA AND CHRONIC PAIN AND HER OPINIONS REGARDING THE INSTRUCTIONS FOR USE ARE UNRELIABLE AND SHOULD BE EXCLUDED

In her report, Dr. Bergmann opines that,

> "Plaintiffs' experts contend the IFU is inadequate because it does not warn of pain or dyspareunia, or because it does not set forth the severity, frequency, or duration of the adverse events that can occur. However, surgeons know that all pelvic floor surgery involves a risk of pain, dyspareunia, recurrence of incontinence, re-operation, infection, wound healing complications, etc. And surgeons know that those adverse events or any others could be temporary or they could be permanent. And they could be mild, moderate, or severe. In my opinion it was and is wholly unnecessary for the IFU to warn of those things."[28]

[26] Ex. C at 17.
[27] Ex. E at 92:6-16.
[28] Ex. C at 19.

However, when confronted with the 2015 TVT IFU, Dr. Bergmann was dumbfounded as to why the IFU included dyspareunia (pain with intercourse) and chronic pain as possible adverse events of the TVT device.

Q And Page 5 continues. There's an "Adverse reaction" section and then an "Other adverse" reaction section, correct?

A Correct.

Q I'll just give you a minute to review that. Let me know when you're finished, please. So would you agree with me that the TVT mesh device can cause all of the items listed in the adverse reactions and other adverse reaction section of this document?

A Well, they have it in here. Again, as I said before, this is something -- some of these are things that I just haven't seen. The recurrence of incontinence, certainly. Bleeding we talked about. Division surgeries.

Q Well, why would Ethicon put these adverse reactions or other adverse reactions in the warnings for their product if they weren't possible?

. . .

THE WITNESS: **I don't know why they would do that. I would assume that it has something to do with either their studies or what they need to do for the FDA**.

Q So is it your testimony that the items that are listed in these two sections, there are some things that are not caused by the TVT device?

A Again, as I said before, some of these things are things I haven't experienced.

Q I didn't ask you what you had experience, I'm asking you if you'll agree with me that these are things that can be caused by the TVT and that's why they are in the instructions for use as potential adverse reactions to the TVT device?

A **Again, I don't know why they would be in there. I have no idea how a TVT would cause chronic pain in the groin. To me, that doesn't make any sense. So as to why they would have something like that in there, I don't know.**

Q Can you let me know what other items you don't believe are possible for the TVT device to cause?

A I'll just go to the first bullet point. Those things can occur. Second bullet point, yes. Third is a warning, absolutely. Fourth, those can occur. Risk of infection, absolutely. Overcorrection, correct. **Acute or chronic pain -- acute pain, yes. Chronic pain, again, that one I'm not so clear as to how the TVT would cause that**. Voiding dysfunction we discussed previously. **The pain with intercourse, as I said, I haven't seen that, so**

> **I'm not sure why that's in there**. We talked about the next bullet point. Recurrence of incontinence we talked about. Bleeding we talked about that that can occur. Revision surgeries are possible, we talked about that, that can occur. And with the last bullet point I would also agree to that.[29] [emphasis added].
> . . .
> Q And do you have any reason to believe Ethicon would put in these additional warnings if they did not believe that it was important and that they were potential adverse reactions to their products?
> . . .
> THE WITNESS: **Again, I don't know why they put them in**.[30] [emphasis added].

Dr. Bergmann also testified that she does not know how the Food and Drug Administration determines product labeling and does not look at FDA regulations as they pertain to medical devices.[31] Dr. Bergmann's opinions regarding the TVT IFU cannot be reliable if Dr. Bergmann does not know why certain adverse reactions are included in the IFU or what adverse reactions the TVT device can cause. Dr. Bergmann's own testimony that she is unaware of what is required for product labeling also disqualifies her from offering said opinions. Dr. Bergmann's opinions regarding the TVT IFU should therefore be excluded.

## VI. DR. BERGMANN'S SELF-CREATED CHART USES AN UNRELIABLE RATING SYSTEM FOR SKILL LEVEL AND COST, SELECTIVE LITERATURE AND CONTAINS INFORMATION NOT RELEVANT TO THIS CASE AND SHOULD BE EXCLUDED

Attached to Dr. Bergmann's report is a chart labeled Table 1 which Dr. Bergmann herself prepared.[32] The table consists of data or conclusions from other studies that Dr. Bergmann "googled" and two categories, Skill Level and Cost, for which Dr. Bergmann created her own rating system.[33] There is no legend or key for Dr. Bergmann's Skill Level or Cost rating system and the "cost" does not take into account cost of any complications or reoperations or related time

[29] Ex. E at 66:4-68:9.
[30] *Id.* at 69:16-22.
[31] *Id.* at 125:11-25.
[32] Ex. C at 22-23; Ex. E at 104:22-105:2.
[33] *Id.* 105:4-11; 107:13-108:8.

off of work for patients.[34] Dr. Bergmann's stated purpose in preparing the table was to make a "very simple way to refer to different types of things rather than write it out as a paragraph or two or five."[35] Dr. Bergmann did not perform an exhaustive search for medical literature or create exclusion or inclusion material, she simply "googled" "studies that address the particular issues that I was trying to compare from one type to another."[36]

Furthermore, the data and percentages included are *not* specific to the TVT but include all retropubic midurethral slings and all transobturator slings.[37] This chart, therefore, contains information that is both unreliable and irrelevant to Dr. Bergmann's opinions which are specific to Defendants' TVT device – not all slings in the universe. Dr. Bergmann's chart should therefore be excluded.

## CONCLUSION

For the reasons above, this Court should grant Plaintiffs' Motion to Exclude Certain Opinions and Testimony of Dr. Cynthia Bergmann, M.D.

Dated: April 21, 2016

Respectfully Submitted,

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[34] *Id.* at 108:2-19.
[35] *Id.* at 106:22-107:12.
[36] *Id.*at 107:13-23.
[37] *Id.* at 105:16-106:18.

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**CERTIFICATE OF SERVICE**

I hereby certify that on April 21, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive services in this MDL.

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